DEPARTMENT OF HEALTH AND HUMAN SERVICES

DDM Display Date 4-14-04
Publication Date 4-15-04
Certifier R. LEDESMA

Food and Drug Administration

[Docket No. 2004N–0158]

# Referral of ZONEGRAN (Zonisamide), WELLBUTRIN and ZYBAN (Bupropion), and RENAGEL (Sevelamer) for the Conduct of Pediatric Studies

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the referral of ZONEGRAN (zonisamide), WELLBUTRIN and ZYBAN (bupropion), and RENAGEL (sevelamer) to the Foundation for the National Institutes of Health (the Foundation) for the conduct of pediatric studies. FDA referred these drugs to the Foundation on November 14, 2003, and is publishing this notice of the referrals.

**FOR FURTHER INFORMATION CONTACT:** Grace Carmouze, Center for Drug Evaluation and Research (HFD–960), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7777.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In accordance with section 4 of the BPCA (Public Law 107–109), FDA is announcing the referral to the Foundation of the written requests for the conduct of pediatric studies for ZONEGRAN (zonisamide), WELLBUTRIN and ZYBAN (bupropion), and RENAGEL (sevelamer). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the exclusivity incentive program described in section 505A of the Federal Food, Drug, and

Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

The BPCA established additional mechanisms for obtaining information on the safe and effective use of drugs in pediatric patients. Specifically, section 4 of the BPCA amends section 505A(d) of the act to create a referral process to obtain studies for drugs that have patent or exclusivity protection, but for which the sponsor has declined to conduct the pediatric studies in response to a written request by FDA. Under section 4 of the BPCA, if the Secretary of Health and Human Services (the Secretary) determines that there is a continuing need for the pediatric studies described in the written request and the sponsors of the products with patent or exclusivity protection have declined to conduct the studies, the Secretary shall refer the drug to the Foundation, established under section 499 of the Public Health Service Act (42 U.S.C. 290(b)), for the conduct of the pediatric studies described in the written request (21 U.S.C. 355a(d)(4)(B)(i)). In addition, the BPCA requires public notice of the name of the drug, name of the manufacturer, and indications to be studied pursuant to the referrals.

In accordance with section 4 of the BPCA, FDA is announcing that it has referred the written request for pediatric studies for ZONEGRAN (zonisamide), WELLBUTRIN and ZYBAN (bupropion), and RENAGEL (sevelamer) to the Foundation. On July 3, 2002, FDA issued a written request for pediatric studies to Elan Pharmaceuticals, the holder of approved applications for ZONEGRAN (zonisamide) that have market exclusivity. The studies described in the written request were for adjunctive therapy in the treatment of partial seizures in the

pediatric population. Elan Pharmaceuticals declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of ZONEGRAN (zonisamide) in the pediatric population.

On July 2, 2002, FDA issued a written request for pediatric studies to GlaxoSmithKline, the holder of approved applications for orally administered WELLBUTRIN and ZYBAN (bupropion) that have market exclusivity. The studies described in the written request were for the indications of depression and smoking cessation in the pediatric population. GlaxoSmithKline declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of WELLBUTRIN and ZYBAN (bupropion) in the pediatric population.

On July 3, 2002, FDA issued a written request for pediatric studies to GelTex Pharmaceuticals, the holder of approved applications for RENAGEL (sevelamer) that have market exclusivity. The studies described in the written request were for the indication of hyperphosphatemia in the pediatric population. GelTex Pharmaceuticals declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of RENAGEL (sevelamer) in the pediatric population.

Consistent with the provisions of the BPCA, on November 14, 2003, FDA referred to the Foundation the written requests for the conduct of the pediatric studies for ZONEGRAN (zonisamide), WELLBUTRIN and ZYBAN (bupropion), and RENAGEL (sevelamer).

Dated: April 7, 2004.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

**BILLING CODE 4160–01–S**